Fact Sheets and Information Papers

Ethylene Oxide (EtO) Sterilizers

March 2005

1. BACKGROUND Sterilizers used in Health Care Facilities commonly employ a combination of dichlorodifluoromethane (CFC-12) and ethylene oxide (EtO). EtO is the actual sterilant, and CFC- 12 as a diluent to form a non-flammable blend. The combination used most often is 12% EtO mixed with 88% CFC-12 and is referred to as "12/88". The CFC-12 is a Class I ozone depleting substance and is being phased out of production. EtO is a hazardous air pollutant (HAP) and is under proposal for federal regulation.

2. REGULATIONS Currently there are two Titles in The Clean Air Act Amendments (CAAA) which govern the use of CFC-12 and EtO. Title VI, section 604 which addresses CFC-12 is a final rule. Title III, section 112 which deals with EtO sterilizers is currently a proposed rule. Both Titles are discussed below:

a. Clean Air Act Amendments (CAAA), Title VI, section 604. Concerned over findings on ozone depletion, the United States and 23 other nations signed the Montreal Protocol on Substances that Deplete the Ozone Layer in September 1987. Timetables were established to reduce the production and use of ozone depleting substances, including CFC-12. In November 1990, President Bush signed the Clean Air Act Amendments (CAAA) of 1990. Title VI, section 604 requires the phase out of CFC production by Dec 31, 1995 and the phase out of CFC use by the year 2000.

b. Clean Air Act Amendments (CAAA), Title III, section 112. The Environmental Protection Agency (EPA) has determined that EtO is a toxic, carcinogenic substance and lists EtO as a hazardous air pollutant. The EPA has proposed a rule that would limit emissions of EtO from existing and new sterilization and fumigation operations. There are several exemptions to this proposal, including the following:

Operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals. **Specifically, hospital sterilizers using EtO are exempt.**

Although Army installations may not be affected by the proposed federal regulation, local and state regulations may be more stringent. Several states regulate EtO sterilizers differently than the proposed federal regulation. Additionally, the EPA is under pressure to retract the hospital sterilizer exemption before final promulgation.

3. ALTERNATIVES The following is a brief summary of the alternatives available. For more detailed information and specifics, contact the appropriate representative listed at the conclusion of the paper.

a. Replace CFC-12 with an acceptable substitute. The EPA's Significant New Alternatives Policy (SNAP) Program became effective 18 April 1994. The SNAP program determines acceptable substitutes for Class I ozone-depleting substances. Below is a list of EPA approved substitutes for CFC-12 for use with sterilants. For more information on the SNAP program, contact the Stratospheric Ozone Information Hotline at (800) 296-1996. The following table addresses substitutes for "12/88." Keep in mind that as a HAP, EtO must comply with federal or state regulations.

Substitute	Comments
CO_2/ETO	CO_2 blends can serve as drop-in replacements to 12/88 in some but not all existing equipment because they require a higher operating pressure.
HCFC-124/EtO	In a blend with EtO, HCFC-124 is the only available drop-in replacement for about half of the equipment using 12/88. Because HCFC-124 is a Class II ozone depleting substance, its use may be subject to future regulation promulgated under section 608 of the CAAA
Pure EtO	Potential exposures of EtO releases can be limited either through the use of catalytic converters which convert waste EtO into CO_2 and water, or through the use of acid water scrubbers which convert waste EtO into ethylene glycol. Must be in accordance with manufacturer recommendations to address flammability concerns. Must be in accordance with OSHA standards to limit occupational exposures
Steam	Applicable only to devices resistant to heat and moisture.[1]

[1]Chart taken from Federal Register Vol. 59 No. 53 Mar 18, 1994 pg 13144.

b. Sterilant (12/88) Recovery & Emission Control Systems. In a simple recovery unit the used 12/88 is recovered from the sterilizer and compressed back into storage tanks. Approximately 70-80% of the sterilant is recovered. The recovered sterilant is then shipped to a reclamation facility for reprocessing. The emission control system takes the recovery unit a step further. After capturing as much of the sterilant as possible, it uses acid scrubbers to convert any non-recoverable sterilant into ethylene glycol.

These systems are compatible with the drop in replacements for CFC-12 mentioned above. Both systems can be retrofited to most current sterilizers. This would involve replacing everything on a sterilizer except the chamber. All of the valving and piping is replaced by copper, brass, and stainless steel piping. A computer control console and printer is also added. Because of the "plumbing" involved with updating the sterilizer and adding the recovery systems, problems with leakage should be considered.

c. 100% EtO with an Abator. This system uses 100% EtO rather than a 12/88 mixture. Because EtO is a HAP, an abator system is used to convert the EtO. The used EtO feeds into a heated air stream where it is diluted and catalytically converted into carbon dioxide and water vapor. Worker exposure issues must be addressed when using 100% EtO. With the 3M system four ounces of 100% EtO are contained in a cartridge which is punctured after the door is closed, locked and the proper conditions are met. There is approximately a 16 hour turn around time with this type of sterilizer.

d. Plasma Sterilization using Hydrogen Peroxide. This process uses hydrogen peroxide and a strong electric field to produce low temperature plasma for sterilization. The primary end products of the process are oxygen and vaporized water which eliminate the need for aeration required with EtO. A single cycle takes about 75 minutes. The system can be fit into a 12 sq. ft. space and requires no venting or special installation, just a 208V outlet. This system is **not** designed for use on cellulosic based products like linen and paper or liquids.

e. Peracetic Acid. The sterilizer is a tabletop unit that uses a single use concentrate of 35% peracetic acid and an anticorrosive dry powder mixture. The sterilizer mixes and dilutes the sterilant to a final concentration of 0.2% peracetic acid. The diluted sterilant has a pH of 6.4 and is noncorrosive to metals. After the cycle is completed the unit flushes the sterile water rinse down the sanitary sewer system. The cycle takes about 25 to 30 minutes depending on the initial water temperature. This is advantageous for items requiring a quick turnaround such as scopes. Also the unit can be used near the procedure room. However, only items that can be totally immersed are eligible for this type of sterilization and only one scope or a small number of instruments can be sterilized in one cycle.

Below is a list of companies offering the above products. Also listed are Army Health Care Facilities which use these products, the POC and the DSN number. The use of trademarked names does not imply endorsement by USACHPPM or the U.S. Army.

<u>Sterilant Recovery and Emissions Control System</u>

Joslyn Sterilizer Corporation
5815 County Rd 41
Farmington, NY 14425
(716) 398-2680

Walter Reed Army Medical Center
(IH) 291-5337

<u>100% EtO Sterilizers</u>

3M HealthCare
3M Center
St Paul, MN 55144
(800) 228-3957

<u>Hydrogen Peroxide Plasma Sterilizer</u> (STERRAD)

Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92718
(800) 755-5900

MEDDAC, Ft Sill
639-3175

Peracetic Acid Sterilizer

Steris Corporation
9450 Pineneedle Dr
Mentor, OH 44060
(800) 548-4873

MEDDAC, Ft Huachuca
821-5111
MEDDAC, Ft Belvoir

Hazardous and Medical Waste Program, Ms. Debbie Hursh
5158 Blackhawk Road, ATTN: MCHB-TS-EHM
Aberdeen Proving Ground, MD 21010-5403
(410) 436-3651, DSN 584-3651

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